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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/307,511	05/07/1999	GUY BOURDON	PBLMD-51494	4934

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EXAMINER

EREZO, DARWIN P

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 12/23/2003

26

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/307,511

Applicant(s)

BOURDON, GUY

Examiner

Darwin P. Erez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 16, 20, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Siemens Servo Ventilator 300, as disclosed in the non patent literature, Operating Manual for Siemens Servo Ventilator 300, in view of US 5,520,172 to Obermayer.

3. As to claim 16, the Siemens Servo Ventilator 300 is a breathing aid device comprising: a patient connection (it is inherent for the ventilator to have a connection to the patient; an inspiratory branch in fluid communication with the patient connection, the inspiratory branch including an inspiration valve (page 17, number 3); an expiratory branch in fluid communication with the patient connection and the inspiratory branch; means for controlling expiration in fluid communication with the expiratory branch, the means for controlling expiration including an expiration valve (page 17, number 11); means for detecting pressure operatively connected to the inspiratory branch (page 17, number 11); and means for ventilating in fluid communication with inspiratory branch, the means for ventilating including means for supplying a breathable gas through the inspiratory branch at an adjustable pressure (pages 82-83), the means for ventilating

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further including means for controlling the inspiration valve and the expiration valve (page 17, number 11), the means for ventilating further including pressure control means for comparing a pressure command to a pressure signal provided by the means for detecting pressure and for adjusting the pressure of the means for supplying (page 83); and means for regulating a patient's breathed volume, the means for regulating including means for controlling volume and means for measuring volume (page 83), wherein the means for controlling volume provides the pressure command to the pressure control means, and wherein the means for measuring volume provides a signal indicative of a measured volume of breathed gas to the means for controlling volume (page 84). The manual for the Siemens Servo Ventilator 300 is silent with regards to the inspiration valve being closed during expiration and the expiration valve is closed during inspiration.

Obermayer teaches a ventilator having an inspiratory branch including an inspiration valve **18**, and an expiratory branch including an expiration valve **13**; wherein the inspiration valve is closed during expiration and the expiration valve is closed during inspiration (col. 3, lines 4-8 and 22-25).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the operation of the Siemens Servo Ventilator 300 in order to have the inspiration valve closed during expiration and the expiration valve closed during inspiration, as disclosed by Obermayer, because it prevents the ventilator from wasting the delivery of breathable gas during expiration.

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4. As to claim 20, the Siemens Servo Ventilator 300 has a means for controlling volume including an input for a minimum inspired volume per cycle, an input for a minimum inspiratory pressure command, and an input for a maximum inspiratory pressure command, wherein the means for controlling volume compares the measured volume from the means for measuring volume with the minimum inspired volume per cycle and adjusts the pressure command in the direction tending to bring the signal from the means for measuring volume toward the minimum inspired volume per cycle, and wherein the means for controlling volume maintains the pressure command within the range of the minimum inspiratory pressure command and the maximum inspiratory pressure command (see page 84).

5. As to claim 24, the Siemens Servo Ventilator 300 is a breathing aid device comprising: a patient connection (it is inherent for the ventilator to have a connection to the patient; an inspiratory branch in fluid communication with the patient connection, the inspiratory branch including an inspiration valve (page 17, number 3); an expiratory branch in fluid communication with the patient connection and the inspiratory branch; an expiration device in fluid communication with the expiratory branch, the expiratory branch including an expiration valve (page 17, number 11); a pressure detector operatively connected to the inspiratory branch (page 17, number 11); a source of breathable gas at an adjustable pressure in fluid communication with the inspiratory branch (page 17, number 3); a valve controller (page 17, number 11; it is inherent for the device to have a controller to control the valves); a pressure controller for comparing a pressure detected by the pressure detector to a pressure command and for adjusting

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the pressure of the source of breathable gas (page 83); a control unit for providing the pressure command to the pressure controller; and a measuring unit for providing a signal to the control unit indicative of a measured volume of breathable gas detected per breathing cycle to the patient connection (page 84). The manual for the Siemens Servo Ventilator 300 is silent with regards to the valve controller closing the inspiration valve during expiration and closing expiration valve during inspiration.

Obermayer teaches a ventilator having an inspiratory branch including an inspiration valve **18**, and an expiratory branch including an expiration valve **13**; wherein the inspiration valve is closed during expiration and the expiration valve is closed during inspiration (col. 3, lines 4-8 and 22-25).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the operation of the Siemens Servo Ventilator 300 in order the inspiration valve closed during expiration and the expiration valve closed during inspiration, as disclosed by Obermayer, because it prevents the ventilator from wasting the delivery of breathable gas during expiration.

6. As to claim 25, the Siemens Servo Ventilator 300 has a means for controlling volume including an input for a minimum inspired volume per cycle, an input for a minimum inspiratory pressure command, and an input for a maximum inspiratory pressure command, wherein the means for controlling volume compares the measured volume from the means for measuring volume with the minimum inspired volume per cycle and adjusts the pressure command in the direction tending to bring the signal from the means for measuring volume toward the minimum inspired volume per cycle, and

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wherein the means for controlling volume maintains the pressure command within the range of the minimum inspiratory pressure command and the maximum inspiratory pressure command (see page 84).

7. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Siemens Servo Ventilator 300, as disclosed in the non patent literature, Operating Manual for Siemens Servo Ventilator 300, in view of Obermayer, and in further view of US 5,353,788 to Miles.

8. The non-patent literature fails to specifically teach the patient connection comprising a facial mask or a nasal mask. Miles teaches that it is known in the art to use a patient connection means comprising a nasal mask **26**, which is also facial mask. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a facial mask or a nasal mask since it is well known in the art to use a nasal mask or a facial mask to connect a patient to a ventilator.

9. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over the Siemens Servo Ventilator 300, as disclosed in the non patent literature, Operating Manual for Siemens Servo Ventilator 300, in view of Obermayer, and in further view of US 4,941,469 to Adaham.

10. The non-patent literature fails to teach an adjustable speed motor-turbine set. Adaham teaches the use of an adjustable motor-turbine set in a ventilator. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was

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made to use the adjustable motor-turbine set of Adaham in the Siemens Servo Ventilator in order to provide air flow to the ventilator.

11. Claims 21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Siemens Servo Ventilator 300, as disclosed in the non patent literature, Operating Manual for Siemens Servo Ventilator 300, in view of US 5,647,351 to Weismann et al.

12. As to claim 21, the Siemens Servo Ventilator 300 is a breathing aid device comprising: a patient connection (it is inherent for the ventilator to have a connection to the patient; an inspiratory branch in fluid communication with the patient connection, the inspiratory branch including an inspiration valve (page 17, number 3); an expiratory branch in fluid communication with the patient connection and the inspiratory branch; an expiration device in fluid communication with the expiratory branch, the expiratory branch including an expiration valve (page 17, number 11); a pressure detector operatively connected to the inspiratory branch (page 17, number 11); a ventilation unit in fluid communication with the inspiratory branch, the ventilation unit including a source of breathable gas at an adjustable pressure (pages 82-83), the ventilation unit further including a valve controller for opening and closing the inspiration valve and the expiration valve (page 17, number 11), wherein the inspiration valve is closed during expiration and the expiration valve is closed during inspiration, the ventilation unit further including a pressure controller for comparing a pressure detected by the pressure detector to a pressure command and for adjusting the pressure of the source

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of breathable gas (page 83); and a regulator for regulating a patient's breathed volume, the regulator including a control unit and a measuring unit, wherein the control unit provides the pressure command to the ventilation unit, and wherein the measuring unit provides a signal indicative of a measured volume of breathed gas to the control unit (page 84). The manual for the Siemens Servo Ventilator 300 is silent with regards to the location of the pressure detector.

Wiesmann teaches that it is well known in the art for a ventilatory support system to have a pressure detector disposed in the patient connection.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to put the pressure detector on the patient connection because it is well known in the art to have a pressure detector disposed in a patient connection to monitor the pressure. Furthermore, the location of the pressure detector is a mere design choice and that the device would work equally well with the pressure detector disposed inside the ventilator unit or the patient connection.

13. As to claim 23, the Siemens Servo Ventilator 300 has a means for controlling volume including an input for a minimum inspired volume per cycle, an input for a minimum inspiratory pressure command, and an input for a maximum inspiratory pressure command, wherein the means for controlling volume compares the measured volume from the means for measuring volume with the minimum inspired volume per cycle and adjusts the pressure command in the direction tending to bring the signal from the means for measuring volume toward the minimum inspired volume per cycle, and wherein the means for controlling volume maintains the pressure command within the

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range of the minimum inspiratory pressure command and the maximum inspiratory pressure command (see page 84).

14. Claims 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over the Siemens Servo Ventilator 300, as disclosed in the non patent literature, Operating Manual for Siemens Servo Ventilator 300, in view of Weismann et al, and in further view of US 4,941,469 to Adaham.

15. The non-patent literature fails to teach an adjustable speed motor-turbine set. Adaham teaches the use of an adjustable motor-turbine set in a ventilator. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the adjustable motor-turbine set of Adaham in the Siemens Servo Ventilator in order to provide air flow to the ventilator.

Response to Arguments

16. Applicant's arguments filed 10/03/2003 have been fully considered but they are not persuasive.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re*

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Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the Obermayer reference teaches an anesthetic machine, in particular for use as ventilation part of an anesthetic system, which provides inspiratory gas to a patient. Similarly, the Siemens Servo Ventilator 300 is a ventilator that provides air to the patient. Therefore, the teaching of closing an inspiration valve during expiration and closing an expiration valve by Obermayer is generally available to one of ordinary skill in the ventilator art because both references deal with providing inspiratory gas to the patient. Furthermore, it would have been obvious to one of ordinary skill in the art to modify the Siemens Servo Ventilator 300 to have the inspiration valve closed during expiration and the expiration valve closed during inspiration, as disclosed by Obermayer, because it prevents the ventilator from wasting the delivery of breathable gas during expiration, which would increase its efficiency and lower its operating cost.

Conclusion

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezzo whose telephone number is (703) 605-0420. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on (703) 308-1957. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

dpe



WEILUN LO
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